SECTION II
REMARKS

Regarding the Amendments

No claims have been amended by the present Response. The claims are pending as set forth in the above Complete Listing of the Claims. As pending, the claims are supported by the specification and the original claims and do not add new matter, as defined by 35 U.S.C. § 132. No amendments are made which would require a new search, or raise new issues for consideration.

Thus, upon entry of the present Response, claims 1-30, 40-42, 62, 63, and 79 are pending and under examination.

Regarding the Restriction Requirement

The examiner has commented that the restriction requirement mailed February 9, 2007 required election of either foreign or endogenous immunogens. As set forth in the Response transmitted on March 9, 2007, applicant elected the species of foreign immunogens and the sub-species of viral proteins. As previously stated, in a species election, if any species is found to be allowable, then additional species will be examined, until all species have been examined. As such, in the present application if viral proteins are found to be allowable, then additional sub-species bacterial proteins, parasite proteins, cytokines, chemokines, and immunoregulatory agents, and therapeutic agents should also be examined. If all of these sub-species are found to be allowable, then additional non-elected species (and sub-species thereof) of immunogens must also be examined. If any generic claim is finally held to be allowable, all claims drawn to species containing all elements of the generic claim will also generally be held to be allowable. (MPEP § 806.04(d)).

The examiner notes that applicant's election of a sub-species of claim 17 is not considered at this time. It is acknowledged that "cellular proteins" of claim 17 is a sub-species of non-elected species "endogenous proteins." However, in the restriction requirement mailed February 9, 2007 it was stated that "[i]f applicants elect foreign immunogens, applicants must also elect one of (a)-

(e) of claim 17..." Applicant provided the election of sub-species cellular proteins in order to be fully responsive to the Office Action mailed February 9, 2007.

In the Response filed July 2, 2007, applicant requested that claims 17 and 18 be rejoined with the presently pending claims. These claims recite non-elected species and there is no requirement that these claims be withdrawn upon election of a different species. Though not acknowledged by the present Office Action, it is noted that claims 17 and 18 are included in the list of pending claims and are not listed as withdrawn. Rejoinder of these claims is assumed by this action and each of these claims is identified by the status identifier "Original" in the above Complete Listing of the Claims.

Rejection of Claims Under 35 U.S.C. §112

Claims 40-42 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement of that section. Claims 40-42 recite a method of vaccination. It is the examiner's allegation that these methods are not enabled by the specification, as filed. Applicant respectfully disagrees.

It is noted that the previous rejection of claims 62-63 has been withdrawn and those claims are considered enabled, under the requirements of 35 U.S.C. § 112, first paragraph.

Specifically, the examiner applies the *In re Wands* factors to the analysis of the lack of enablement of rejected claims 40-42. Applicants submit that an analysis of such factors leads to the conclusion that one of skill in the art would have been enabled to perform the claimed methods of vaccination. The examiner alleges that analysis of the *In re Wands* factors "Nature of the Invention," "State of the Art," "Guidance in the Specification" and "Working Examples" are insufficient to provide enablement to the methods of claims 40-42 (method of vaccination by administering a vaccine). The examiner states that "[i]n view of the lack of guidance, objective evidence, and predictability in the specification, it would require undue experimentation by one of ordinary skill in the art to practice the claimed invention." (Office Action mailed September 13, 2007, page 4.) Applicant respectfully disagrees.

Nature of the Invention

In a statement under the "Nature of the Invention" heading, the examiner states that "the claims encompass the prevention of diseases by administering a vaccine." The examiner's attention is respectfully drawn to the language of claim 40 and claims 41 and 42 dependent therefrom. Specifically, claim 41 recites "[a] method of vaccination, comprising administering to a subject the rdsRP according to claim 4 in an amount to express an effective amount of an encoded passenger gene." While the claims recite a method of vaccination, the claims do not specifically recite a method of preventing diseases or any other use of a vaccine. A vaccine, by definition, is administered to establish immunity to a disease. The claimed method of vaccination therefore accomplishes such establishment of immunity by expression of an effective amount of an encoded passenger gene.

Claim 40 and claims 41 and 42 dependent therefrom are drawn to a method of vaccination comprising administering rdsRP (of claim 4) to a subject. The amount of rdsRP is an amount sufficient to express an effective amount of an encoded passenger gene. No further use of the vaccine is recited in claims 40-42.

State of the Art

In describing the "State of the Art," the examiner states that "...nearly any protein when inoculated can cause an immune reaction, the prophylactic nature of this reaction is not guaranteed and has to be experimentally determined." (Office Action mailed September 13, 2007, page 3; emphasis removed from original.)

It is respectfully submitted that by the "Guidance in the Specification" and "Working Examples," provided in the application, as discussed below, the prophylactic nature of the administration to a subject of an the rdsRP of claim 4 (a rdsRP encoding a double stranded RNA eukaryotic expression cassette for expression in eukaryotic cells, the rdsRP comprising at least one segment of a dsRP and an IRES nucleotide sequence incorporated into the at least one segment of the dsRP, where the rdsRP further comprises at least one passenger gene sequence incorporated into the at least one segment of the dsRP, wherein the passenger gene and the IRES are functionally linked) and expression of an effective amount of the encoded passenger gene is shown.

Guidance in the Specification and Working Examples

It is well established that

> "[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA 1970)." (MPEP §2164.01(b); emphasis added.)

The elements of the claimed method of claims 40-42 are clearly set forth in the specification. Specifically, methods of making rdsRP are detailed at pages 7-8 and 12-14; sources of IRES sequences are described at pages 8-9; examples of genes of interest that can be inserted in dsRP are described at pages 9-12. All of this would clearly allow one of skill in the art to make a rdsRP for use in the method of claims 40-42.

With regard to using the constructed rdsRP in a method of vaccination, establishing immunity to a disease, the examiner's attention is respectfully drawn to the specification at pages 19-21, where it is discussed in detail how the rdsRP can be administered to dendritic cells *in vitro*, how rdsRP vaccines are formulated, how rdsRP vaccines are administered to animal tissues and how rdsRP are orally administered.

Furthermore, examples 8-11, while prophetic, provide detailed direction to one of skill in the art with regard to infection of human dendritic cells *in vitro* with rdsRP (Example 8), immunogenicity of rdsRP vaccine vectors in mice (Example 9), measurement of immune responses (Example 10), and vaccination protocol discrimination criteria (Example 11). It is stated in the MPEP that "[a]n example may be 'working' or 'prophetic'...[but an] applicant need not have actually reduced the invention to practice prior to filing...only an enabling disclosure is required." (MPEP §2164.02)

One of skill in the art would have combined the teachings of human dendritic cells *in vitro* with the *in vivo* mouse vaccinations and would have found the combination to be reasonably predictive of the efficacy of the claimed methods of vaccination comprising administration to a subject of an the rdsRP of claim 4 and expression of an effective amount of an encoded passenger gene.

Accordingly, withdrawal of the rejection of claims 40-42 for lack of enablement under 35 U.S.C. §112, first paragraph, is respectfully requested.

Double Patenting

Claims 1-30, 62-63 and 79 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 7,018,835 ("the '835 patent").

To overcome such nonstatutory double patenting rejections, a Terminal Disclaimer is enclosed herewith for filing. Payment of the Statutory Disclaimer fee of **$65.00** (small entity) pursuant to 37 CFR 1.20(d) is authorized in the enclosed Credit Card Payment Form PTO-2038.

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CONCLUSION

Based on the foregoing, all of Applicants' pending claims 1-30, 40-42, 62, 63, and 79 are patentably distinguished over the art, and are in form and condition for allowance. The Examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

The time for responding to the September 13, 2007 Office Action without extension was set at three months, or December 13, 2007. This response is therefore timely and no fees are believed to be due for the filing of this paper. However, should any fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

Date: November 13, 2007

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